



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,937	08/21/2007	Anna Cederholm	EPCL:015US/ 10613209	6786
33425 7590 09/02/2010 FULBRIGHT & JAWORSKI L.L.P. 600 CONGRESS AVE. SUITE 2400 AUSTIN, TX 78701				
EXAMINER				
WEN, SHARON X				
ART UNIT		PAPER NUMBER		
1644				
NOTIFICATION DATE		DELIVERY MODE		
09/02/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

aopatent@fulbright.com

Office Action Summary

Application No.

10/599,937

Applicant(s)

CEDERHOLM ET AL.

Examiner

SHARON WEN

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-6 and 8-13 is/are pending in the application.
- 4a) Of the above claim(s) 1, 6, 8, 9 and 11-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-5 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after Final Rejection. Since this application is eligible for continued Examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/11/2010 has been entered.

2. Applicant's amendment, filed 07/26/2010, has been entered.

Claims 2 and 7 have been canceled.

Claim 4 has been amended.

Claims 1, 3-6, 8-13 are pending.

Claims 1, 6, 8, 9 and 11-13 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Inventions, there being no allowable generic or linking claim. Election was made *without* traverse in the reply filed on 07/28/2009.

Claims 3-5 and 10 are currently under examination as they read on a method of preventing plaque rupture in a subject.

3. This Action will be in response to Applicant's Arguments/Remarks, filed 07/26/2010.

The rejections of record can be found in the previous Office Action, mailed 04/26/2010.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 4 and 10 are rejected under 35 U.S.C. 102(a)(e) as being anticipated by Blackenberg et al. (US 2003/0152513 A1, cited on IDS, see entire document).

Applicant's argument has been considered but has not been found convincing for reasons of record and reiterated below for Applicant's convenience:

Blackenberg taught a method of preventing plaque rupture in a subject comprising administering annexin V (see, e.g., Abstract and Brief Summary of the Invention on pages 2 and 3). In particular, Blackenberg taught treating subject exhibiting vulnerable plaque which reads on preventing plaque rupture in the subject (see paragraph [0034]). Moreover, Blackenberg taught an effective amount of annexin V to be administered for therapeutic purpose (see paragraph [0031]).

In response to Applicant's argument that the newly added "active component" limitation has distinguished the present claims from the prior art teaching because the prior taught that annexin V was used a binding molecule, it is noted that under the broadest reasonable interpretation, annexin V is an active component because its activity is binding the cellular target. Therefore, the rejection is maintained as it applies to the amended claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blackenberg et al. (US 2003/0152513 A1, cited on IDS) in view of Manzi (Rheumatology 2000, 39:353-359).

Applicant's argument has been considered but has not been found convincing for reasons of record and reiterated below for Applicant's convenience:

The teaching by Blackenberg has been discussed supra. Blackenberg did not teach that the subject is a SLE patient. However, it would have been obvious to one of ordinary skill in the art, at the time of the invention was made, to use annexin V to prevent plaque rupture in SLE patient because SLE patients are known to have a greater risk of plaque rupture as taught by Manzi (see entire document, in particular, see Endothelial cell injury on page 354 and Figure 1 on page 355). Therefore, one of ordinary skill in the art would have been motivated to use Annexin V to treat vulnerable plaque as taught by Blackenberg in SLE patients who are more susceptible to plaque rupture as taught by Manzi (see, e.g., Figure 1).

Furthermore, one of ordinary skill in the art would also have been reasonably expected determine the effective amount of annexin V to administer in view of the teaching by Blackenberg that annexin V can be used for imagine diagnosis of vulnerable plaque by the treating physicians (see paragraph [0034]). Since the effective amount of Annexin V is a result effective variable which is related to the dosage range of the administration, the person of ordinary skill in the art would have been able to select an effective amount of annexin V by optimizing the dosage of annexin V based on the imagine diagnosis using labeled annexin V to bind endothelium in the subject.

Therefore, the invention, as a whole, was *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's argument and Examiner's rebuttal are essentially same as above.

Given that Blackenberg taught using annexin V in the treatment, and under the broadest reasonable interpretation, annexin V is an active component of the treatment.

Therefore, the rejection is maintained as it applies to the amended claims.

Conclusion

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON WEN whose telephone number is (571)270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571)272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Wen/
Examiner, Art Unit 1644
August 28, 2010